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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,514	02/19/2002	Ludwig Volkel	52203	3431

7590 08/04/2003

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Washington, DC 20036

EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/04/2003

6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/076,514

Applicant(s)

VOLKEL ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2003 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____ .
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION

Acknowledgment of Papers Received: Extension of time and Amendment/Response dated 5/22/03

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackett et al (USPN 2,774,759) in view of Klein et al (USPN 2,870,198), both in further view of Spires (USPN 4,394,377). The claims are drawn to a crystalline choline ascorbate. The claims recite that the choline ascorbate is free from water of crystallization. The claims are also drawn to a process of making the choline comprising reacting ascorbic acid with trimethylamine and ethylene dioxide at a temperature between -10⁰C and 40⁰C. The claims also recite specific diffraction characteristics of the crystalline choline ascorbate. The claims go on to recite possible uses and embodiments for the choline ascorbate.

Blackett discloses a choline ascorbate produced by reacting trimethylamine and ethylene oxide at 30⁰C (col. 1, lin. 15 – col. 3, lin. 13). The choline ascorbate has its water content removed through vacuum (Examples). The choline salts can be isolated by conventional means

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(col. 2, lin. 56 – 60). Though silent to the effect crystallization is well-known and conventional means of isolating a salt, as seen in Klein.

Klein discloses choline salts, which are crystallized at relatively low temperatures (col. 2, lin. 61 – 68). The crystals are processed with trimethylamine and ethylene oxide at temperatures below 40 degrees Celsius (examples). The reference acknowledges that the greatest purity for the choline salts is achieved through the crystallization process described therein (col. 3, lin. 12 – 43). Though silent to the effect, it would be well within the level of ordinary skill in the art to apply these processing steps to the ascorbic acid salt of choline, specifically the choline of Blackett.

With regard to claims 3 – 5 which recite the diffraction characteristics of the compound, it is the position of the examiner that these characteristics would be inherent to the compound recited in the art. Presented here is a crystalline choline ascorbate free from water of crystallization, and processed from reacting ascorbic acid, trimethylamine and ethylene oxide, at a temperature below 40⁰C. Barring a showing of unexpected results or evidence to the contrary it is the position of the examiner that the compounds of the present invention and the compound recited by the art are identical, hence having identical properties including diffraction characteristics. The diffraction information claimed can be determined through routine experimentation by artisans of ordinary skill and do not impart patentability on the formulation.

Also the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the

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claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With regard to claims 10 and 11, it is well known that all choline acid salts have a utility as dietary supplements, as seen by Spire (USPN 4,394,377). Spire discloses embodiments where choline ascorbate and other salts are incorporated into pharmaceutical formulations and feed preparations (col. 4, lin. 28 – 35; col. 5, lin. 1 – 18). It would be obvious to include the particles attainable through the process of Klein into a formulation of Spire since they would have improved purity.

With these things in mind it would have been obvious to a skilled artisan to combine the teachings of the references. It would have been obvious to follow the suggestion of Blackett to isolate the choline salts by conventional means including the crystallization of Klein in order to improve the purity of the formulation. It would have been obvious to include the crystals into a preparation as described by Spire, in order to deliver a purer choline salts preparation to those in need. It would have been obvious to combine the teachings and suggestions of the art with an expected result of a dietary supplement comprising a purer choline ascorbate.

Response to Arguments

3. Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young
August 3, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600